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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,138	10/06/2003	Hiroaki Oka	63979-034	3982

7590 10/17/2005

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EXAMINER	
WOOD, AMANDA P	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/678,138	**Applicant(s)** OKA ET AL.
	Examiner Amanda P. Wood	**Art Unit** 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *13-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Claims 1-12 in the reply filed on 3 August 2005 is acknowledged.

Claims 13-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3 August 2005.

Currently, Claims 1-12 are pending. This office action is in response to the reply filed on 3 August 2005.

Specification

The disclosure is objected to because of the following informalities:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). Appropriate correction is required.

The abstract of the disclosure is objected to because it exceeds one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Petersen et al (US 6,682,649).

Petersen et al teach a method of measuring activity signals of a biological sample (i.e., making electrophysiological measurements of the current flow through a cell membrane or other ion channel-containing structure) in the Abstract of the disclosure. Petersen et al further teach the use of a porous substrate (i.e., a perforated silicon substrate) whereby measurement chambers (also called, e.g., sites, wells, or test confinements) are created that have measurement electrodes on at least one side. The method taught by Petersen et al also provides for the use of suction to pass the target liquid (carrier liquid) through the substrate, therefore establishing a giga seal between the substrate and biological sample (cell), allowing for measurement of the biological sample's activity signals through the measurement electrode (see, e.g., col. 3, lines 30-55). Petersen et al further teach that a plurality of electrodes can be contained on the substrate, creating a plurality of measurement chambers, or sites, allowing for several different measuring set-ups on a substrate. Therefore, different (or the same) target liquids (e.g., liquids containing different test samples, including pharmacological drugs) could be introduced (i.e., injected) to a plurality of different measurement chambers associated with a plurality of different measurement electrodes (see, e.g., col. 5, lines 10-65 and col. 17, lines 1-20).

Furthermore, Petersen et al teach a method wherein a conductor is formed on the porous insulating substrate via a mask layer, and is electrically connected to the measurement electrode (see, e.g., col. 8, lines 15-60). The method described by Petersen et al provides several different options for deposition of the conductor onto the substrate for formation of the electrode, one of which is sputtering (see, e.g., col. 7, lines 50-67).

Therefore, the cited reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al (US 6,682,649) in view of Owen et al (WO 99/663290).

The primary reference is relied upon for the reasons set forth above. This reference reasonably teaches a method of measuring activity signals of a biological sample – as instantly claimed.

Petersen et al do not expressly teach the use of a particular porous insulating substrate. In claim 6, applicant refers to a porous insulating substrate composed of a resin film, having pore diameter between 1 μm and 1000 μm. Owen et al beneficially teach a method of using a porous substrate to monitor ion channel activity in a biological membrane (see, e.g., Abstract). Owen et al specifically point out that the porous substrate used may be any number of materials, including polytetrafluorotethylene (PTFE) and polyethylene terephthalate, both of which are considered to be resin-type materials (see, e.g., page 12, lines 5-10). Owen et al also teach that the diameter of the substrate pores should be between 1 μm and 7μm (see, e.g., page 11, lines 15-20). Owen et al further teach that it would be beneficial to use such a porous insulating substrate so as to provide a means for screening a large number of samples, as well as to provide a means for a cell and substrate to create a high-resistance seal which would allow for monitoring of ion channel activity in a biological membrane (see, e.g., Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make result-effective adjustments of conventional working conditions and/or design-choice parameters within such methods for measuring the activity signals of a biological sample (e.g., using a particular porous insulating substrate with particular thickness and pore diameter, as beneficially discussed by

Owen et al) based upon the overall beneficial teaching provided by the cited reference. The result-effective adjustment of particular conventional working conditions (e.g., using the measurement chamber and porous insulating substrate for more than one measurement of a target liquid or replacing the porous insulating substrate after each different target liquid is tested and/or evaluating the activity of such a biological sample based upon the conventional calculation of the standard deviation, mean value, and half-width of the obtained normal distribution of data collected) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.P. Wood

APW

A. P. Wood
Examiner, AU 1655

CHRISTOPHER R. TATE
PRIMARY EXAMINER